02/OPP#00675

2SPP

RECEIVED
SEP 21 2000
PUBLIC DOCKET

Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States

Issued jointly by

United States Environmental Protection Agency

and

Canada Pest Management Regulatory Agency

under the auspices of

The NAFTA Technical Working Group on Pesticides

August 30, 2000

1922

TABLE OF CONTENTS

I OBJECTIVE 3

II CURRENT LEGAL FRAMEWORK IN THE UNITED STATES 3
- A The Federal Insecticide, Fungicide and Rodenticide Act 3
- B The Federal Food, Drug and Cosmetic Act 4
- C The Federal Seed Act 4

III CURRENT LEGAL FRAMEWORK IN CANADA 5
- A Pest Control Products Act 5
- B Food and Drugs Act 5
- C Seeds Act 6

IV COMPARISON OF US AND CANADIAN LEGAL FRAMEWORK 6

V COMPARISON OF US AND CANADIAN DATA REQUIREMENTS 6
- A Product Chemistry 7
- B Toxicology 7
- C Exposure (Occupational and Bystander) 7
- D Food, Feed Residue Studies 7
- E Environmental Fate and Ecological Effects 8
- G Value Data 8
- F Addition of a Seed Treatment Use to an Existing Registration 8

VI CONCLUSIONS 8

VII APPENDIX ONE 10
Comparison of US and Canadian Legal Framework 10

VIII APPENDIX TWO 12
Seed Treatment Data Requirements for Canada
(Seed Treatments Food and Feed, PMRA USC # 10) and the United States
(EPA Terrestrial Food Crop Use Group) 12

I OBJECTIVE

The purpose of this document is to provide information on how seed treatment products are currently regulated in both Canada and the United States and to review the degree of regulatory harmonization of these commodities in the two countries. This discussion regarding treated seed should also contribute toward the realisation of the initiatives of the NAFTA Technical Working Group on Pesticides aimed at harmonizing pesticide registration requirements in Canada, the United States, and Mexico.

For the purposes of this document seed treatments include products which are primarily intended to provide protection against soil fungi and insect damage. Seeds for propagation may be treated domestically or imported as treated seed, may be treated domestically for subsequent export, or may be planted to produce crop that is to be exported.

II CURRENT LEGAL FRAMEWORK IN THE UNITED STATES

A The Federal Insecticide, Fungicide and Rodenticide Act

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), a pesticide generally must be registered with the EPA in order to be distributed, sold or to be imported into the United States. To be registered, the EPA must determine that the pesticide will not pose unreasonable adverse effects to man or the environment. The EPA has the authority however, under FIFRA sec. 25(b) to exempt a pesticide from any provisions of FIFRA including registration, if the pesticide is "adequately regulated by another Federal agency" or "of a character that is unnecessary to be subject to [FIFRA] in order to carry out the purposes of the Act"

For the purposes of FIFRA, pesticide-treated seeds are considered to be pesticides themselves because they are a mixture of substances that are intended to prevent, destroy, repel or mitigate a pest. In 1988, the EPA promulgated regulation 40 CFR 152.25(a) exempting certain treated articles (including treated seeds) from regulation under FIFRA provided that both of the following conditions are met:

a) the pesticide used for the treatment is registered for such use.

b) the treatment is for the protection of the article or substance itself.

In issuing this regulation, the EPA reasoned that the risks of treated seeds that meet the above criteria could adequately be regulated by means of registration of the treating pesticide. In evaluating the risks of the seed treatment, the EPA could also evaluate the risks from exposure to the seed treated according to the label instructions and forgo the need for a separate evaluation

and registration of the treated seed.

The term "registered for such use"in 40 CFR 152.25(a) refers to registration in United States under FIFRA, and not to registration processes in other countries. Seeds treated in foreign countries are not eligible for the exemption unless they are treated with a pesticide also registered in the US.

The term "for the protection of the [seed] itself" means that the pesticidal protection imparted to the treated seed does not extend beyond the seed itself to offer pesticidal benefits or value attributable to the treated seed. Unless claims of pesticidal benefit or value attributable to the treated seed and extending beyond the treated seed are made in conjunction with the distribution or sale of the treated seed within United States, the EPA will presume that the seed will have been treated "for the protection of the seed itself." The EPA does not regard a statement that seed has been treated (e.g., Seed has been treated with [a particular pesticide active ingredient] as a protectant) as a pesticidal claim that would negate the exemption outlined in 40 CFR 152.25a.

In general, seed treated with a pesticide that is to be sold or distributed in the United States must be coloured to prevent diversion for animal feed or other non-planting uses. EPA regulations in 40 CFR 153.155 require that a pesticide registered for treating seeds must contain a suitable dye unless the treatment is applied at-planting (e.g., in the hopper box) for which dye is not necessary, or unless the pesticide label requires the user treating the seed to separately add a dye during the seed treatment process.

Seeds for planting which are treated with pesticides registered in the US are exempt from registration as pesticides, and may be freely distributed and sold within the United States. Sellers, distributors, and importers of treated seeds should maintain sufficient documentation of the treatment to demonstrate that the treating pesticide is registered in the United States.

B The Federal Food, Drug and Cosmetic Act

Under Federal Food, Drug and Cosmetic Act (FFDCA) sec. 408, the EPA evaluates the risks posed by pesticide residues in food and feed to a standard of "a reasonable certainty of no harm". Before registration, a pesticide tolerance (or exemption) must be established if the intended use of the pesticide may result or may reasonably be expected to result, directly or indirectly, in residues in a food crop. Treated seed for planting of food crops requires a tolerance unless it can be shown that residues are not carried forward to the crop grown from the seed. Generally, tolerances established as a result of the assessment of a foliar use for a particular crop are adequate to cover use as a seed treatment.

Under the FFDCA, the Food and Drug Administration has established a policy with respect to the colouration of grain seeds to prevent the diversion into animal feed. Grain seed treated with pesticides for which there are no tolerances set or in excess of an established tolerance is required to be coloured or discoloured to avoid being considered adulterated. Although the policy applies

only to certain grain seeds, it is widespread practice for other treated seed to be so coloured to indicate the presence of a pesticide.

C The Federal Seed Act

The Federal Seed Act (FSA) and its regulations establish labelling requirements for seeds treated with toxic pesticides, both domestic and imported. Treated seeds must be labelled or tagged, or information concerning the treatment of bulk seed must be provided in invoices. In general, the following information is required: 1) a statement that seeds have been treated; 2) the common name of the treating pesticide; 3) a warning not to use for food, feed or oil purposes, and 4) if toxic, a skull and crossbones and the word POISON. The regulations outline exceptions and other provisions and should be consulted for complete information.

III CURRENT LEGAL FRAMEWORK IN CANADA

A Pest Control Products Act

In Canada, the PMRA administers the Pest Control Products Act (PCPA) which requires that all pest control products be assessed as to their safety, merit, and value.

The PCPA regulations require that seeds (including seed-like fruits, bulbs, corms, and rootstock) treated with a pest control product be registered unless exempted from registration under certain conditions specified in Schedule II of the regulations, as follows:

a) the product used to treat seed is registered in Canada for that specific purpose **and**

b) the seed is sold and shipped in bulk and shipping documents bear information setting forth the common name or chemical name of the active ingredient of the control product used to treat the seed; **and**

c) where the seed is packaged, the package bears a label with the words "This seed is treated with" followed by the name of the control product including the common name or chemical name of its active ingredient together with the appropriate precautionary symbols and signal words selected from Schedule III and such other statements as are required by these regulations and applicable to the control product used to treat the seed.

In addition, Section 42 of the Regulations requires that "Where the physical properties of a control product are such that the presence of the control product may not be recognized when used and is likely to expose a person or domestic animal to a severe health risk, the control product shall be denatured by means of colour, odour, or such other means as the Minister may approve to provide a signal or warning as to its presence."

B Food and Drugs Act

In Canada, the Food and Drugs Act (FDA) prohibits the sale and distribution of contaminated and adulterated food. Regulations indicate when an adulterant is 'unacceptable', e.g., in the case of agricultural chemicals, whenever the residue exceeds the prescribed Maximum Residue Limit (MRL). In the absence of a specific MRL for a pesticide, a maximum limit of 0.1 ppm is used.

In the case of pesticide treated seed, the seed is not considered a food (due to colouration, labelling, and packaging which prevent its diversion to food) therefore MRLs are not set for treated seeds. However crops grown from treated seeds may potentially have a residue and so there remains a need to evaluate potential residues as part of any risk assessment.

C Seeds Act

The Seeds Act (SA) regulates all seeds, including those treated with pest control products. The SA defines seed as any plant part of any species belonging to the plant kingdom, represented, sold, or used to grow a plant.

Section 20 of the SA regulations requires that any seed treated with a pest control product "shall be thoroughly stained with a conspicuous colour to show that the seed has been so treated," unless the seed has been coated with any material that itself renders the seed conspicuous. Where seed has been treated with a pest control product, the precautionary symbol and signal word prescribed by the regulations made under the PCPA to indicate the degree and nature of risk inherent in that product, together with the following statement marked on the package of the seed or on a conspicuous label attached to the package, are required:

"Do not use for food or feed. This seed has been treated with . . . (common or chemical name of pest control product)."

IV COMPARISON OF US AND CANADIAN LEGAL FRAMEWORK

Both Canada and the United States require registration of seed treatment products used for domestic seed treatment. Both countries allow exemptions for imported pesticide-treated seeds providing the seed is treated with a pesticide registered in the host country for that specific purpose and where certain other conditions are met (e.g., compliance with colouration and labelling requirements). As summarized in the attached Appendix One which compares the legal framework in the US and Canada, both countries have essentially similar labelling, colouration, and packaging requirements to mitigate risk associated with handling of the treated seed and to prevent its diversion to use as a food or feed.

V COMPARISON OF US AND CANADIAN DATA REQUIREMENTS

The general data requirements for a new seed treatment formulated with an unregistered active ingredient are provided in the attached Appendix Two. This table is a side by side comparison of

requirements of the EPA Terrestrial Food Crop Use Group and the PMRA Use Site Category #10, Seed Treatments, Food and Feed. It should be noted that although EPA categorizes seed treatments as a Terrestrial Food Crop, for the purposes of this table, EPA has, where possible, evaluated those requirements as they apply to seed treatments only. The table demonstrates that US and Canadian data requirements are essentially harmonized although there remain some differences. The EPA and PMRA are continuing to work to resolve differences.

Requirements for each of the major data categories are discussed below. The additional data requirements for a new seed treatment product where a foliar food use is also proposed or already registered for a particular active ingredient are also briefly discussed.

A Product Chemistry

The PMRA and EPA product chemistry requirements are essentially identical. It should be noted that, with the exception of storage stability data, the properties listed as "R" for PMRA and "CR" for EPA under 2.14 (TGAI) and 3.5 (EP) in Appendix II are in fact equivalent. The PMRA requires either data or a waiver request for each of these properties and the basis for waiver requests (as per Dir98-03 and Dir908-04 notes) is consistent with EPA's property conditions (as per 40 CFR §158.190 notes).

B Toxicology

Acute toxicology requirements are similar for both countries. However, the US requires an additional short term study (21-day dermal). Both countries require separate oncogenicity studies. The US requires both microbial point and mammalian point mutation genotoxicity studies whereas Canada requires only one of these studies along with an in vitro chromosomal aberration genotoxicity study. The US requires a short term neurotoxicity study while Canada only conditionally requires this study. The PMRA intends to upgrade its toxicological data requirements to harmonize with those of the EPA and would currently accept a seed-treatment product for review that met EPA toxicology requirements.

C Exposure (Occupational and Bystander)

Canada requires exposure data which includes an exposure estimate based on the Pesticide and Handlers Exposure Database (PHED) or other data base; mixer/loader/applicator and post application passive dosimetry and post application monitoring data while these are only conditionally required by the EPA.

D Food, Feed Residue Studies

In the US, registration of a product as a seed treatment requires a tolerance unless it can be shown

using a radio-labelled study that there is no residue uptake (<5 ppb) in the plant grown from the treated seed. Consequently, Appendix Two indicates a number of residue chemistry data requirements associated with the need to establish a tolerance, including multiresidue analytical methods, supervised residue trials, temporal residue data and analytical residue reference standards. If the required radio-labelled study indicates no uptake, no tolerance would be required and these data would not be required. Such data are only conditionally required in Canada.

In addition, on October 27, 1999, the EPA issued a policy statement entitled "Threshold of Regulation, Determinating Whether a Pesticide With a Food Use Pattern Needs a Tolerance." This statement, which is available on the EPA website (**www.epa.gov/pesticides/trac/science/#residues),** is an alternative approach to the establishment of tolerances that may be applicable to seed treatment residue data requirements.

E Environmental Fate and Ecological Effects

The environmental data requirements are similar for both countries. The PMRA. However, requires terrestrial field dissipation studies conducted in appropriate North American ecoregions at relevant sites, whereas the EPA conditionally requires these data for seed treatments. With respect to ecotoxicology, the EPA requires non-target plant data, while the PMRA does not for seed treatments.

G Value Data

The requirement that efficacy data be submitted for review is specific to Canada. Although US registrants are required to conduct efficacy trials, they are not required to provide such data to the EPA.

F Addition of a Seed Treatment Use to an Existing Registration

The data requirements discussed above represent the full data package for a seed treatment formulated with a new, unregistered active ingredient. Registration of a product for use as a seed treatment is frequently requested subsequent to or in addition to other proposed food uses and may therefore only require a subset of the data outlined above.

Many of the data requirements will have been satisfied where a seed treatment use is requested for a pesticide which is already registered as a foliar use on a particular crop. Addition of a seed treatment use to an existing foliar registration would require only data associated with registration of the specific end-use product intended for the seed treatment, typically product chemistry and acute toxicology studies and in Canada, efficacy data. In the US, a tolerance for the foliar use will, in most cases, cover residues resulting from seed treatment; thus data needed to establish a tolerance will not be needed. Depending on the active ingredient and previously registered uses, data may be conditionally required for worker exposure, food residues, field dissipation and avian toxicity.

In conclusion data outlined in Appendix Two which has already been submitted and reviewed to support a foliar application of a particular end-use product to a food crop, may be cited in support of an application for use of the same product as a seed treatment.

VI CONCLUSIONS

The legal framework for the registration of seed treatment products in Canada and the United States are essentially harmonized. Although data requirements are not identical, they are essentially harmonized in most areas, and the EPA and the PMRA continue to work to resolve differences.

Trade irritants are most frequently the result of dissimilar registrations in the two countries and consequently commodity grower groups and users are encouraged to work with pesticide registrants to ensure that appropriate applications are submitted simultaneously to both countries. Full use of existing joint review and work sharing mechanisms between the two countries, as well as minor use programs, should be made to minimize dissimilar registrations and resulting trade irritants.

Minor differences in data requirements are likely resolvable in the context of a joint review submission, a process which both Agencies strongly encourage registrants to pursue. Presubmission consultations are required in the joint review process to establish case-specific data requirements (including possible data waivers) and differences can be resolved or justified prior to a submission being made.

VII APPENDIX ONE

Comparison of US and Canadian Legal Framework

United States Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)	Canada Pest Control Products Act (PCPA)
Pesticide-treated seeds are considered to be pesticides themselves because they are mixtures of substances used to prevent, destroy, repel or mitigate a pest. Regulation 40 CFR 152.25(a) exempts certain treated articles (including treated seeds) from regulation under FIFRA provided the following conditions are met: a) the pesticide used for the treatment is registered for such use. b) the treatment is for the protection of the article or substance itself. Treated seeds that are to be sold or distributed in the United States must be coloured to prevent diversion for animal feed or other non-planting uses. Regulation 40 CFR 153.155 requires that a pesticide registered for treating seeds must contain a suitable dye **unless** the treatment is applied in the hopper box at-planting or **unless** the pesticide label requires the user treating the seed to separately add a dye to the seed treatment process.	The PCPA requires that all pest control products be assessed as to safety, merit, and value. Seeds (including seed-like fruits, bulbs, corms, and rootstock) treated with a pest control product be registered unless exempted from registration under conditions specified in Schedule II of the Regulations: a) the product used to treat seed is registered in Canada for that specific purpose **and** b) where the seed is sold and shipped in bulk that shipping documents bear information setting forth the common name or chemical name of the active ingredient of the control product used to treat the seed; **and** c) where the seed is packaged, the package bears a label with the words "This seed is treated with" followed by the name of the control product including the common name or chemical name of its active ingredient and the appropriate precautionary symbols and signal words. Section 42 of the Regulations requires that "Where the presence of the control product may not be recognized when used; the control product shall be denatured by means of colour, odour, or such other means."

Federal Food, Drug and Cosmetic Act (FFDCA)	Food and Drugs Act (FDA)
Under Sec. 408 FFDCA, The risks posed by pesticide residues in food and feed is assessed under a standard. "reasonable certainty of no harm" Before registration, a food crop must have a pesticide tolerance (or exemption). Treated seed for planting of food crops must have a tolerance unless it can be shown that residues are not carried forward to the crop grown from seed. Generally, tolerances established as a result of assessment of a foliar use are adequate to cover seed treatment use Grain seed treated with pesticides for which there are no tolerances set or in excess of an established tolerance must be coloured or discoloured to avoid being considered adulterated. (Although the policy applies only to certain grain seeds, it is widespread practice for other treated seed to be so coloured to indicate the presence of a pesticide.)	Prohibits the sale and distribution of contaminated and adulterated food and requires that Maximum Residue Limits (MRL) be established for agricultural chemicals. MRLs are not set for pesticide treated seed, as the seed is not considered to be a food due to colouration, labelling, and packaging which prevent its diversion to food. Crops grown from treated seeds may potentially have a residue and so there remains a need to evaluate potential residues as part of any risk assessment.
Federal Seed Act (FSA)	**Seeds Act (SA)**
Treated seeds must be labelled or tagged, or for bulk seed, invoices must provide information concerning the pesticide treatment. Required information includes: 1) a statement that seeds have been treated; 2) the common name of the treating pesticide; 3) a warning not to use for food, feed or oil purposes 4) if toxic, a skull and crossbones and word POISON.	Section 20 of SA regulations requires that any seed treated with a pest control product " shall be thoroughly stained with a conspicuous colour to show that the seed has been so treated", unless the seed has been coated with any material that itself renders the seed conspicuous. The precautionary symbol and signal word prescribed by the PCPA regulations together with the following statement marked on the package of the seed or on a conspicuous label attached to the package, is required: "Do not use for food or feed. This seed has been treated with . . . (common or chemical name of pest control product)."

VIII APPENDIX TWO

Seed Treatment Data Requirements for Canada (Seed Treatments Food and Feed, PMRA USC # 10) and the United States (EPA Terrestrial Food Crop Use Group)

Seed Treatment Data Requirements				
Canada PMRA Data Code	Title	USC # 10	US EPA Guidelines Reference Number	Terrestrial Food Crop
0	**Index**	**R**		
1	**Label**	**R**		
2	Chemistry requirements for the registration of a technical grade of active ingredient (TGAI) or an integrated system product.			
2.1	Applicant's Name and Office Address	R		
2.2	Manufacturer's Name and Office Address and Manufacturing Plant's Name and Address	R		
2.3	Product Trade Name	R	830.1000	R
2.3.1	Other Names	R	830.1000	R
2.4	Common Name	R	830.1550	R
2.5	Chemical Name	R	830.1550	R
2.6	Chemical Abstracts Registry Number	R	830.1550	R
2.7	Structural Formula	R	830.1550	R
2.8	Molecular Formula	R	830.1550	R
2.9	Molecular Weight	R	830.1550	R
2.11	**Manufacturing Methods for the TGAI**			
2.11.1	Manufacturing Summary	R	830.1620	R
2.11.2	Description of Starting Materials	R	830.1600	R
2.11.3	Detailed Production Process Description	R	830.1620	R
2.11.4	Discussion of Formation of Impurities	R	830.1670	R
2.12	**Specifications**			
2.12.1	Establishing Certified Limits	R	830.1750	R
2.12.2	Control Product Specification Form	R	830.1550	R
2.13	**Preliminary Analysis**			
2.13.1	Methodology/Validation	R	830.1700	CR
2.13.2	Confirmation of Identity	R	830.1700	CR
2.13.3	Batch Data	R	830.1000 830.1700	R
2.13.4	Impurities of Toxicological Concern	CR	830.1700	CR

Seed Treatment Data Requirements				
Canada PMRA Data Code	Title	USC # 10	US EPA Guidelines Reference Number	Terrestrial Food Crop
2.14	**Chemical and Physical Properties**			
2.14.1	Colour	R	830.6302	R
2.14.2	Physical State	R	830.6303	R
2.14.3	Odour	R	830.6304	R
2.14.4	Melting Point / Melting Range	R	830.7200	CR
2.14.5	Boiling Point / Boiling Range	R	830.7220	CR
2.14.6	Density or Specific Gravity	R	830.7300	R
2.14.7	Water Solubility (mg/L)	R	830.7840 830.7860	R
2.14.8	Solvent Solubility (mg/L)	R	830.1000	R
2.14.9	Vapour Pressure	R	830.7950	R
2.14.10	Dissociation Constant	R	830.7370	R
2.14.11	Octanol/Water Partition Coefficient	R	830.7550 830.7560 830.7570	R
2.14.12	UV/Visible Absorption Spectra	R	830.7050	R
2.14.13	Stability (Temperature, Metals)	R	830.6313	R
2.14.14	Storage Stability Data	CR	830.6317	CR
2.15	Sample(s) of Analytical Standards and ROC	R	830.1900	CR
2.16	Other Studies/Data/Reports	CR		
3	**Chemistry Requirements for the Registration of Manufacturing Concentrates and End-Use Products Formulated from Registered technical grade of active ingredients or integrated system products.**			
3.1	**Product Identification**			
3.1.1	Applicant's Name and Office Address	R		
3.1.2	Formulating Plant's Name and Address	R		
3.1.3	Trade Name	R	830.1000	R
3.1.4	Other Names	R	830.1000	R
3.2	**Formulation Process**			
3.2.1	Description of Starting Materials	R	830.1600	R
3.2.2	Description of the Formulation Process	R	830.1650	R
3.2.3	Discussion of the Formation of Impurities of Toxicological Concern	CR	830.1670	R
3.3	**Specifications**			
3.3.1	Establishing Certified Limits	R	830.1750	R
3.3.2	Control Product Specification Form	R	830.1550	R

Seed Treatment Data Requirements				
Canada PMRA Data Code	Title	USC # 10	US EPA Guidelines Reference Number	Terrestrial Food Crop
3.4	**Product Analysis**			
3.4.1	Enforcement Analytical Method	R	830.1800	R
3.4.2	Impurities of Toxicological Concern	CR	830.1800	R
3.5	**Chemical and Physical Properties**			
3.5.1	Colour	R	830.6302	R
3.5.2	Physical State	R	830.6303	R
3.5.3	Odour	R	830.6304	R
3.5.4	Formulation Type	R	none	none
3.5.5	Container Material and Description	R	none	none
3.5.6	Density or Specific Gravity	R	830.7300	R
3.5.7	pH	R	830.7000	CR
3.5.8	Oxidizing or Reducing Action (Chemical Incompatibility)	R	830.6314	CR
3.5.9	Viscosity	R	830.7100	CR
3.5.10	Storage Stability Data	R	830.6317	CR
3.5.11	Flammability	R	830.6315	CR
3.5.12	Explodability	R	830.6316	CR
3.5.13	Miscibility	R	830.6319	CR
3.5.14	Corrosion Characteristics	R	830.6320	R
3.5.15	Dielectric Breakdown Voltage	R	830.6321	CR
3.6	Sample(s)	CR	830.1900	CR
3.7	Other Studies/Data/Reports	CR		
4	**Toxicology**			
4.1	Summaries - Toxicology Profile	R		
4.2	**Acute Studies - TGAI**			
4.2.1	Acute Oral	R	870.1100	R
4.2.2	Acute Dermal	R	870.1200	R
4.2.3	Acute Inhalation	R	870.1300	R
4.2.4	Primary Eye Irritation	R	870.2400	R
4.2.5	Primary Dermal Irritation	R	870.2500	R
4.2.6	Dermal Sensitization	R	870.2600	R
	Acute Neurotoxicity - rat	----	870.6200	R
4.3	**Short-Term Studies - TGAI**			
4.3.1	Short-Term Oral (90 day) (rodent)	R	870.3100	R
4.3.2	Short-Term Oral (Non-rodent, e.g. dog)	R	870.3100	R
4.3.6	Short-Term Inhalation (90 day)	CR	870.3465	CR

14822

Seed Treatment Data Requirements				
Canada PMRA Data Code	Title	USC # 10	US EPA Guidelines Reference Number	Terrestrial Food Crop
	21-Day Dermal	----	870.3200	R
	90-Day Dermal	----	870.3250	CR
	28-Day delayed neurotoxicity - hen	----	870.6100	CR
4.4	**Long-Term Studies TGAI**			
4.4.1	Chronic (rodent)	R (4.4.1 and 4.4.2 can be combined as 4.4.4)	870.4100	R
4.4.1	Chronic (non-rodent)		870.4100	R
4.4.2	Oncogenicity (rodent species 1 e.g. mouse)	R (see 4.4.1)	870.4200	R
4.4.3	Oncogenicity (rodent species 2 e.g. rat)	R	870.4200	---
4.4.4	Combined Chronic/Oncogenicity (rodent)	CR (see 4.4.1)	870.4200	R
4.5	**Special Studies TGAI**			
4.5.1	Multigeneration-Reproduction (rodent)	R	870.3800	R
4.5.2	Teratogenicity (rodent)	R	870.3700	R
4.5.3	Teratogenicity (non-rodent)	R	870.3700	R
4.5.4	Genotoxicity: Microbial Point Mutation	CR	870.5265	R
4.5.5	Genotoxicity: Mammalian (cell) Point Mutation	CR	870.5300	R
4.5.6	Genotoxicity: *In vitro* Chromosomal Aberrations	R	none	none
4.5.7	Genotoxicity: *In vivo* Chromosomal Aberrations	R	870.5380 870.5385 870.5395	R
4.5.8	Other Genotoxicity Studies	CR	none	none
4.5.9	Metabolism/Toxicokinetics in Mammals (laboratory animal)	R	870.7485	R
4.5.10	Acute Delayed Neurotoxicity	CR	870.6100 (hen)	CR
4.5.11	Short-Term Neurotoxicity	CR	870.6200	R
	Domestic Animal Safety	---	870.7485	CR
	Dermal Penetration	---	870.7600	CR
4.6	**Acute Studies - EP**			

15722

Seed Treatment Data Requirements				
Canada PMRA Data Code	Title	USC # 10	US EPA Guidelines Reference Number	Terrestrial Food Crop
4.6.1	Acute Oral	R	870.1100	R
4.6.2	Acute Dermal	R	870.1200	R
4.6.3	Acute Inhalation	R	870.1300	R
4.6.4	Primary Eye Irritation	R	870.2400	R
4.6.5	Primary Dermal Irritation	R	870.2500	R
4.6.6	Dermal Sensitization	R	870.2600	R
4.7	**Short-Term Studies - EP**			
4.7.1	Short-Term Oral (90 day)	CR	none	none
4.7.3	Short-Term Dermal (90 day)	CR	none	none
4.7.4	Short-Term Dermal (21-day, 30-day)	CR	870.3200	—
	Short-Term Dermal (90-day)	----	870.3250	----
4.7.5	Short-Term Inhalation (90 day)	CR	none	none
4.7.6	Short-Term Inhalation (21-day, 30-day)	CR	none	none
4.8	Other Studies/Data/Reports	CR	none	none
	Domestic Animal Safety	----	870.7200	CR
	Dermal Penetration	----	870.7600	CR
5	**Exposure (Occupational and/or Bystander) (EP)**			
5.1	Summaries	R	none	none
5.2	Use Description/Scenario (Application and Post Application)	R	875.1700 875.2700 875.2800	CR
5.3	Pesticides Handlers Exposure Database Assessment (or other database)	R	none	none
5.4	Mixer/Loader/Applicator- Passive Dosimetry Data	R	875.1100 875.1200 875.1300 875.1400	CR
5.5	Mixer/Loader/Applicator-Biological Monitoring Data	R	875.1500	CR
5.6	Post Application-Passive Dosimetry Data (Includes dermal and inhalation exposure)	R	875.2400 875.2500	CR
5.7	Post Application-Biological Monitoring Data	R	875.2600	CR
5.8	Dermal Absorption	CR	870.7600	CR
5.9	Dislogeable Residues (Foliar, Soil and Surface)	----	875.2100	CR
5.11	Glove/Clothing Penetration Data	CR	none	none

Seed Treatment Data Requirements				
Canada PMRA Data Code	Title	USC # 10	US EPA Guidelines Reference Number	Terrestrial Food Crop
5.13	Package Integrity Study	CR	none	none
5.14	Other Studies/Data/Reports	CR	none	none
6	**Metabolism/Toxicokinetics Studies (TGAI or EP)**			
6.1	Summaries	R		
6.2	Livestock	CR	860.1300	CR
6.3	Plants	R	860.1300	R
6.4	Other Studies/Data/Reports	CR		
7	**Food, Feed and Tobacco Residue Studies EP**			
7.1	Summaries	R		
7.2	**Analytical Methodology (Food Crops & Tobacco)**			
7.2.1	Supervised Residue Trial Analytical Methodology	R	860.1340	R
7.2.4	Analytical Methodology (Multi-Residue Analytical Methodology)	----	860.1360	R
7.3	Freezer Storage Stability Tests	CR	860.1380	CR
7.4	**Crop Residue Data**			
7.4.1	Supervised Residue Trial Study	CR	860.1500	R
7.4.2	Temporal Residue Study	CR	860.1500	R
7.4.3	Confined Crop RotationTrial Study	CR	860.1850	CR
7.4.4	Field Rotation Crop Data	CR	860.1900	CR
7.4.5	Processed Food/Feed	CR	860.1520	CR
7.4.6	Residue Data for Crops Used as Livestock Feed	CR	860.1500	CR
7.5	Livestock, Poultry, Egg and Milk Residue Data (from feeding of treated crops)	CR	860.1480	CR
7.8	Other Studies/Data/Reports	CR		
	EPA ONLY			
	Analytical Reference Standards	----	860.1650	R

Seed Treatment Data Requirements				
Canada PMRA Data Code	Title	USC # 10	US EPA Guidelines Reference Number	Terrestrial Food Crop
8	Environmental Chemistry and Fate			
8.1	Summaries	R		
8.2	**Laboratory Studies of Physicochemical Properties**			
8.2.1	Summary to Include: Solubility in Water, Vapour Pressure, Octanol: Water Partition Coefficient, Dissociation Constant, UV-Visible Absorption, Density or Specific Gravity (See parts 2 and 3)	R		R
8.2.2	**Analytical Methodology (parent compound and transformation products)**			
8.2.2.1	Soil	R	840.1100 (footnote #12)	R
8.2.2.4	Biota	R	850-1950 850-2500 (footnote # 17)	CR
8.2.3	**Laboratory Studies of Transformation (TGAI)**			
8.2.3.1	Summary	R		
8.2.3.2	Hydrolysis	R	835.2120	R
8.2.3.3	**Phototransformation**			
8.2.3.3.2	Water	R	835.2410	R
8.2.3.3.3	Air	CR	835.2370	---
8.2.3.4	**Biotransformation in Soil (TGAI)**			
8.2.3.4.2	Aerobic Soil 20°-30°C	R	835-4100	R
8.2.3.4.4	Anaerobic Soil 20°-30°C	R	835-4200	R
8.2.3.6	Special Studies Related to Use-Pattern or Formulation	CR		
8.2.3.5	**Biotransformation in Aquatic Systems (TGAI)**			
8.2.3.5.2	Aerobic Water 20°-30°C	CR[1]	835.4300	CR
8.2.4	**Laboratory Studies of Mobility (TGAI)**			
8.2.4.1	Summary	R		
8.2.4.2	Adsorption/Desorption	R	835.1230	R

[1] For aquatic uses only

18222

Seed Treatment Data Requirements				
Canada PMRA Data Code	Title	USC # 10	US EPA Guidelines Reference Number	Terrestrial Food Crop
8.2.4.5	Volatilization	CR	835.1410	CR
8.2.4.6	Special Studies Related to Use-Pattern or Formulation (EP) e.g. special seed leaching study	CR		CR
8.3	**Field Studies of Dissipation/Accumulation [May be Small or Large-Scale] (EP)**			
8.3.1	Summary	R		
8.3.2.	Terrestrial	R	840.1100	CR
8.3.4	Special Studies Related to Intended Use Pattern	CR		
8.4	**Storage, Disposal and Decontamination (TGAI & EP)**			
8.4.1	Summary	R		
8.5	**Other Environmental Fate Studies (TGAI & EP)**			
8.5.1	Summary	CR		
8.6	Other Studies/Data/Reports	CR		
9	**Environmental Toxicology**			
9.1	Summary	R		
9.6	**Wild Birds**			
9.6.1	Summary [2]	R		R
9.6.2	**Acute Studies**			
9.6.2.1	Oral (LD50) Bobwhite Quail	R	850.2100	R
9.6.2.2	Oral (LD50) Mallard Duck	CR	850.2100	---
9.6.2.3	Oral (LD50) Other Species	CR	850.2100	---
9.6.2.4	Dietary (LC50) Bobwhite Quail	R	850.2200	R
9.6.2.5	Dietary (LC50) Mallard Duck	R	850.2200	R
9.6.2.6	Dietary (LC50) Other Species	CR	850.2200	---
9.6.3	**Chronic Studies**			
9.6.3.1	Avian Reproduction Bobwhite Quail	R	850.2300	R
9.6.3.2	Avian Reproduction Mallard Duck	R	850.2300	R
9.6.3.3	Avian Reproduction Other Species	CR	850.2300	---
9.6.4	Laboratory Studies with End-Use Product (EP)	CR	850.2500	CR
9.6.5	Field Studies (EP)	CR	850.2500	CR

[2] Summary should include number of seeds/unit weight of seeds, weight of ai/unit weight of seeds and number of seeds applied/unit area"

9822

Seed Treatment Data Requirements				
Canada PMRA Data Code	Title	USC # 10	US EPA Guidelines Reference Number	Terrestrial Food Crop
9.6.6	Special Studies Related to the Intended Use-Pattern	CR		
9.7	**Wild Mammals (TGAI)**			
9.7.1	Summary	CR		
9.7.2	Field Studies (EP)	CR	850.2400 850.2500	---
9.9	Other Studies/Data/Reports	CR		
9.5.2	**Non-Target Fresh Water Organisms**			
9.5.2.1	Cold Water Fish (rainbow trout)	R	850.1075	R
9.5.2.2	Warm Water Fish (bluegill sunfish)	R	850.1075	R
9.3.2	*Daphnia* sp. Acute	R	850.1010	R
9.3.3	*Daphnia* sp. Chronic (Life-Cycle)	CR	850.1300	CR
	Fish early Life Stage	CR	850.1400	CR
9.4	**Non-Target Estuarine / Marine Organisms (TGAI)**			
9.4.2	Acute (Crustacean)	CR	850.1025	CR
9.4.5	Chronic (mollusc or crustacean)	CR	850.1300	CR
9.5.2.4	Acute Estuarine Fish	CR	850.1035	CR
9.5.3.2	Chronic Fish Life Cycle	CR	850.1500	CR
9.8	Non-Target Plant Studies (10 terrestrial species)	---		R (Tier I)
10	**Value (applicable to each pest/site or host combination)**			
10.1	Value Summaries	R		
10.2	**Efficacy Studies**			
10.2.1	Mode of Action	R	none	
10.2.2	Description of Pest Problem	R	none	
10.2.3	**Efficacy Trials**			
10.2.3.1	Summaries	R		
10.2.3.2	Efficacy: Laboratory, Growth Chamber Trials	CR	none	
10.2.3.3	Efficacy: Small-scale Trials (Field, Greenhouse)	R	none	
10.2.3.4	Efficacy: Operational Trials	CR	none	
10.3	**Adverse Effects on Use Site**			

Seed Treatment Data Requirements				
Canada PMRA Data Code	Title	USC # 10	US EPA Guidelines Reference Number	Terrestrial Food Crop
10.3.1	Summaries	CR	none	
10.3.2	Non-Safety Adverse Effects [e.g.: to crop, host animal, site of application (discolouration, corrosion), etc.]	CR	Tier I: 850.4200 850.4100 850.4150 850.4400 850.5400 Tier II: 850.4200 850.4225 850.4400 850.5400 Tier III: 850.4300 850.4450 850.4025	
10.3.3	Damage to Rotational Crops	CR	none	
10.4	Economics	CR	none	
10.5	**Sustainability**			
10.5.1	Survey of Alternatives (chemical and non-chemical)	CR	none	
10.5.2	Compatibility with Current Management Practices Including IPM	CR	none	
10.5.3	Resistance Management	CR	none	
10.5.4	Contribution to Risk Reduction	CR	none	
10.6	Other Studies/Data/Reports	CR		

21822

Seed Treatment Data Requirements				
Canada PMRA Data Code	Title	USC # 10	US EPA Guidelines Reference Number	Terrestrial Food Crop
12.5	**Foreign Reviews**			
12.5.2	Foreign Reviews of Chemistry Requirements for TGAIs or Integrated System Products	CR		
12.5.3	Foreign Reviews of Chemistry Requirements for MAs and EPs formulated from registered TGAIs or ISPs	CR		
12.5.4	Foreign Reviews of Toxicology	CR		
12.5.5	Foreign Reviews of Exposure (Occupational and/or Bystander)	CR		
12.5.6	Foreign Reviews of Metabolism / Toxicokinetics Studies	CR		
12.5.7	Foreign Reviews of Food, Feed and Tobacco Residue Studies	CR		
12.5.8	Foreign Reviews of Environmental Chemistry and Fate	CR		
12.5.9	Foreign Reviews of Environmental Toxicology	CR		
12.5.10	Foreign Reviews of Value	CR		
12.7	**Comprehensive Data Summaries**	R		